#15 Appeal Brief 9/24/02 [illegible]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s): Connell et al.
Appl. No.: 09/711,240
Filed: November 13, 2000
Title: METHOD AND APPARATUS FOR KIDNEY DIALYSIS
Art Unit: 1723
Examiner: J. Drodge
Docket No.: ALT-5604D CON II of DIV III

Commissioner for Patents
Washington, DC 20231

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on July 11, 2002. This Appeal is taken from the Final Rejection dated April 11, 2002.

I. REAL PARTY IN INTEREST

The real party in interest is Baxter International Inc., by way of Assignment dated December 19, 2000.

II. RELATED APPEALS AND INTERFERENCES

Appellants know of no related appeals or interferences that will directly affect or be directly affected by or have a bearing on this Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 30-41 are pending in the application. Claims 30-41 stand rejected under 35 U.S.C. § 103 by final Office Action dated April 11, 2002. Attached hereto as the Appendix is a copy of Claims 30-41 that are on appeal.

IV. STATUS OF AMENDMENTS

No amendments were filed after the final rejection. However, Appellants are submitting herewith a Declaration under 37 C.F.R. § 1.132 and request that it be entered of record.

V. SUMMARY OF INVENTION

The invention relates generally to, inter alia, improved hemodialysis machines comprising features previously unavailable on hemodialysis machines. Application, page 1, lines 13-15. An important feature of the subject hemodialysis machines and of the claims at issue is the touch screen (Application, page 76, lines 11-12; Application, page 13, line 29 to page 23, line 19) which one expert identified as "[t]he key feature" of the invention. Sadler Declaration of record, ¶ 10.

On the priority date of the present application, the use of a touch screen as a user interface for certain types of medical equipment was known in the art. Application, page 13, lines 31-37 (incorporating by reference U.S. Patent No. 4,898,578 to *Rubalcaba Jr.*, and U.S. Patent No. 4,974,599 to *Suzuki*). However, Appellants were the first to invent a hemodialysis machine including and utilizing a touch screen as a user interface.

More specifically, the touch screen, used as an interface for a hemodialysis machine, can provide a large number of parametric displays and controls for the operator. Even if the entire front panel of a conventional machine were dedicated to accommodating as many discrete and complex displays and controls as possible, the touch screen of a hemodialysis machine as claimed could still replace a greater number of, and a more complex array of, such displays and controls. Using the touch screen, the operator of a claimed hemodialysis machine can select which displays and controls to depict and actuate. See, e.g., Application, page 14, line 33 to page 15, line 12; Application, FIGS. 8-11. The touch screen also performs any of various user prompts and other menu-guided protocols, which renders even complex dialysis therapy easy to perform after minimal operator training. Application, page 19, lines 12-22.

Also, by eliminating virtually all discrete displays and controls from the hemodialysis machine, the touch screen effectively eliminates a serious problem with conventional hemodialysis machines: cumbersome and time-consuming cleaning and disinfection procedures that were required with conventional machines whenever any body fluid (e.g., blood) contacted the machine. The many discrete displays and controls on a conventional hemodialysis machine present a large number and variety of crevices and other confined spaces on surfaces of the machine that are prone to accumulate drips and splashes of body fluids. If, for example, a blood

leak occurs onto the front surface of a conventional machine (a very common occurrence in a dialysis clinic), the attendant danger of transmission of AIDS, hepatitis, or other blood-borne disease requires that the machine be removed temporarily from service for extensive surficial cleaning and disinfection. The machine is removed from service because such cleaning and disinfection frequently requires at least partial disassembly of affected controls and displays to gain access to blood that has entered a crevice or other tight space around or beneath the controls and displays. The touch screen, in contrast, presents a smooth sealed surface that allows a surficial spill of blood or other body fluid thereon to be quickly and easily cleaned and disinfected without having to disassemble anything or otherwise remove the machine from service. The touch screen therefore offers a major advantage in busy dialysis clinics that operate on very tight budgets (as virtually all dialysis clinics do).

The touch screen also facilitates easy programming of any of various time-varying hemodialysis parameters such as variable bicarbonate and variable ultrafiltration. See, e.g., Application, page 16, line 17 to page 18, line 28. The operator enters profile data by directly touching points on a bar graph displayed on the touch screen. Id. The ease of such programming is enhanced by the highlighting (on the touch screen) of certain "buttons" or other icons to guide the user, even a novice user, through the programming routine. Application, page 14, line 14 to page 19, line 22.

VI. ISSUES

A. Did the Examiner properly establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in rejecting Claims 30-41 for alleged obviousness from *Lichtenstein's* U.S. Patent No. 4,370,983 in combination with *Rubalcaba, Jr.'s* U.S. Patent No. 4,898,578 and/or *Kerns* et al.'s U.S. Patent No. 4,756,706?

B. Does the objective evidence of secondary considerations being submitted herewith traverse this same obviousness rejection, particularly evidence demonstrating industry acclaim, long-felt need, market success, and copying by others?

VII. GROUPING OF CLAIMS

The claims currently pending can be grouped into eight groups by dependency relationships. Independent Claims 30, 31, 32, 33, 40, and 41 stand alone. Claims 35 and 36 depend from independent Claim 34, while Claims 38 and 39 depend from Claim 37.

In the argument presented below, each of the pending independent claims embodies a unique combination of patentable features. Therefore, for purposes of this appeal, each claim or group of claims is separately patentable.

VII. ARGUMENT

A. The Examiner did not properly establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a)

1. Obviousness of a patent claim is a legal conclusion based on four underlying factual inquiries and requires some motivation to combine references.

A patent may not be granted for an invention "if the differences between the subject matter sough to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Obviousness is a legal conclusion properly based upon four factual inquiries: (1) the scope and content of the prior art; (3) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective indicia of obviousness. *ATD Corporation v. Lydall, Inc.*, 159 F.3d 534, 546, 48 U.S.P.Q. 2d 1321, 1329 (Fed.Cir. 1998), citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86 S.Ct. 684 (1966) (other citations omitted).

In addition to these four factual inquiries, the cited prior art references must include some teaching or suggestion to combine the references; otherwise, an examiner would be tempted to use hindsight gathered during examination of the claimed invention to defeat the patentability of that invention. *ATD Corporation*, 159 F.2d at 546, 48 U.S.P.Q. 2d at 1329; *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q. 2d 1453, 1457-1458 (Fed.Cir. 1998); *see generally* Donald S. Chisum, *Chisum on Patents*, § 5.04[1][e][ii] (Matthew Bender, 1999). "In other words, the

examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d at 1357, 47 U.S.P.Q. 2d at 1458. Indeed, this requirement for some teaching or suggestion for combining prior art references in creating an obviousness rejection "stands as a critical safeguard against hindsight analysis..." *In re Rouffet*, 149 F.3d at 1358, 47 U.S.P.Q. 2d at 1458.

Three possible sources of a motivation to combine multiple prior art references are: (1) the nature of the problem to be solved; (2) the teachings of the prior art; (3) the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 149 F.3d at 1357, 47 U.S.P.Q. 2d at 1458. The question of obviousness generally rests on whether there is something in the prior art as a whole to suggest the desirability of combining separately disclosed elements. *In re Rouffet*, 149 F.3d at 1356, 47 U.S.P.Q. 2d at 1456. If no such teaching or suggestion for combining prior art references exists, then the case for obviousness "suffers a significant deficiency." *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 U.S.P.Q. 2d 1378, 1384 (Fed.Cir. 1997); *see also ATD Corp.*, 159 F.3d at 546, 48 U.S.P.Q. 2d at 1330 (reversing a jury verdict of obviousness because no substantial evidence of such teaching or suggestion existed in the prior art, or in the general knowledge of persons of ordinary skill in the art in the field). In fact, "[t]he absence of such suggestion to combine is dispositive in an obviousness determination." *Gambro Lundia AB*, 110 F.3d at 1579, 42 U.S.P.Q. 2d at 1383.

On appeal, an obviousness rejection may be overcome by a showing that the examiner reached an incorrect conclusion of obviousness. *In re Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q. 2d at 1455.

2. The Examiner did not establish a *prima facie* case for obviousness because he failed to identify a substantial motivation for combining the cited prior art references to yield the claimed combinations of elements, and improperly applied the cited references with hindsight.

The Examiner rejected Claims 30-41 under 35 U.S.C. § 103(a) for alleged obviousness from U.S. Patent No. 4,370,983 to *Lichtenstein* (termed herein "*Lichtenstein*") in view of U.S.

Patent No. 4,898,578 to *Rubalcaba Jr.* (termed herein "*Rubalcaba*") and/or U.S. Patent No. 4,756,706 to *Kerns* et al. (termed herein "*Kerns*"). Office Action dated April 11, 2000, page 3, ¶ 1.

Lichtenstein describes an extracorporeal blood circulation and treatment system, including modules for drug infusion that can be controlled by a computer. *Lichtenstein* does not disclose a touch screen as a user interface for the computer and does not suggest the need for a touch screen. The Examiner contends that a combination of a touch screen with a hemodialysis machine according to the subject claims is obvious because *Kerns* and *Rubalcaba* allegedly teach the use of a touch screen with a modular drug-infusion pumping system

Both *Kerns* and *Rubalcaba* disclose similar portable modular infusion-pump systems for delivering medicaments to a patient. *Rubalcaba*, column 3, lines 21-27; *see also*, *Kerns*, column 2, lines 45-59 and column 12, lines 3-4. Each drug-infusion module is mechanically identical (*see, e.g.,* FIG. 1 of *Kerns*; FIG. 1 of *Rubalcaba*), but each is used for supplying a different drug to the patient. Neither *Kerns* nor *Rubalcaba* describes an extracorporeal blood-treatment system, a hemodialysis system, operating a hemodialysis system, or what parameters are pertinent to operating a hemodialysis system.

A modular drug-infusion system according to either *Rubalcaba* or *Kerns* can display limited patient information obtained from sensors such as an oxymeter or blood pressure monitor (*Kerns*, column 2, lines 49-59), and can calculate, display, and store a separate set of parameters for each infusion module (*Rubalcaba*, column 8, lines 35-41). However, adding a touch screen to a hemodialysis machine is not the same as simply adding a different style of gauge or changing an arrangement of controls; rather, providing a hemodialysis machine with a touch screen requires extensive innovation in hardware and software. This is due, in part, to the fact that a hemodialysis machine is a complex apparatus with a large number of components that must be controlled very accurately and precisely to ensure patient safety and comfort. Moreover, combining *Lichtenstein*'s extracorporeal blood-treatment system with features disclosed in *Kerns* or *Rubalcaba* is not taught nor suggested by any of these references.

Lichtenstein provides no teaching, suggestion, hint, or any other indication leading a skilled artisan to contemplate incorporating a touch screen with the disclosed computerized

blood-treatment system. Whereas *Lichtenstein* does disclose computer control of a medical device (*see, e.g.,* column 2, lines 52-68), *Lichtenstein* provides no hint whatsoever that a user interface for the device can be a touch screen or anything like a touch screen. Therefore, the skilled artisan reading this reference on the priority date of the present application would understand that the user-machine interfaces disclosed in Lichtenstein are perfectly suited for their intended purposes. Moreover, no further alterations to hemodialysis machine controls or improvements to user interface are required or even contemplated by this reference.

Lichtenstein also fails to disclose any teaching or suggestion whatsoever as to why a touch screen would be beneficial or desirable in a hemodialysis machine, how a touch screen could incorporate the complex controls and displays necessary in a hemodialysis machine, what operating parameters could be controlled or displayed using a touch screen, or how data concerning any operating parameters of a hemodialysis machine could be displayed or changed using a touch screen. Neither *Kerns* nor *Rubalcaba* provides any hint to a skilled artisan regarding how to develop or integrate the complex software and hardware required to replace some or all the electromechanical controls and displays of a conventional hemodialysis machine with a functional touch screen. The respective apparatus described in *Kerns* and *Rubalcaba* are directed primarily to modular drug-infusion pump systems based on a "central management unit" connected to a plurality of (*e.g.,* four) identical pumping modules. *See, e.g., Kerns*, FIG. 1 and column 2, lines 49-59; *Rubalcaba*, FIG. 1 and column 3, lines 8-27. The central management unit calculates drug-delivery rates based on data supplied by the user. *See, e.g., Kerns*, column 10, lines 18-68; *Rubalcaba*, column 4, line 22 to column 5, line 68. However, neither reference provides any teaching or suggestion of how to go about comprehensively monitoring and controlling the multitude of complex parameters inherent in operating a hemodialysis machine using a touch screen or any other user interface.

The Examiner contends that each of *Kerns* or *Rubalcaba* suggests combining a touch screen with a hemodialysis machine. With respect to *Kerns*, the Examiner specifically cited column 1, lines 41-59 as the basis for his contention. The cited text of *Kerns* summarizes the use of a central management unit, not a touch screen, to control a number of mechanically identical drug-infusion modules connected to the central management unit. The central management unit is used to control the internal setup of the modules and to receive and display information from

the modules (which are normally stacked atop one another during operation). The central management unit is also used for the following purpose:

> In order to prevent confusion of data due to the detachment and reattachment of modules in possibly different orders, the central management unit of this invention automatically keeps track of the identity of various modules regardless of their position in the module stack attached to the central management unit.

Kerns, column 1, lines 54-59. However, this cited text in *Kerns* does not mention a touch screen or suggest why combining a touch screen with a hemodialysis machine would be desirable. Any "confusion of data" identified in *Kerns* arises solely from the switching and rearrangement of different drug-infusion modules in the stack. The explicitly stated object of the *Kerns* apparatus addresses this problem:

> It is therefore the object of the invention to provide a portable, centrally-managed integral set of selectively removable modular units for pumping and monitoring purposes, each unit being adapted to be programmed and monitored through the central management unit but being capable of functioning independently when detached therefrom.

Kerns, column 2, lines 7-13.

In contrast, hemodialysis machines are not modular in the manner described in *Kerns*. A hemodialysis machine does not include multiple modules that are subject to "switching" or other mixups in a stack and hence must be kept track of. Therefore, the expressed object in *Kerns* of preventing confusion of data in the context of multiple, identical, stackable pump modules does not extrapolate, based on *Kerns*, to providing any teaching or suggestion of combining a touch screen with a hemodialysis machine.

Rubalcaba sought to correct another problem peculiar to modular drug-infusion systems by:

> providing a system with a touch screen calculator arrangement that automatically calculates, displays, and stores a separate set of parameter values for each one of the infusion pump modules.

Rubalcaba, column 2, lines 8-11. This feature provided a specialized calculator capable of retaining data when the drug-infusion modules were switched on the stack. *Cf.*, *Rubalcaba*, column 1, line 56 to column 2, line 4. According to *Rubalcaba*, the specialized calculator, in the context of multiple stacked infusion-pump modules, substantially lowered the chance for user confusion and error. *Rubalcaba*, column 8, lines 40-41.

The benefits described in *Rubalcaba* are described only in the context of a system having multiple separate drug-infusion pump modules used to provide respective drugs to a patient. The modules require coordinated programming and frequently are interchanged on a stack. Hence, some manner of "keeping track" of them is required. This problem did not exist with hemodialysis machines on the priority date of the instant application. *Rubalcaba* provides no disclosure or suggestion that a hemodialysis machine, as known on the priority date of the instant application, had any problem with "user confusion and error" in this same described context. It goes without saying that "user confusion and error" is highly machine-specific. What causes user confusion and error in a stack of pump modules is not, without more information than *Rubalcaba* provides, the same as what could cause user confusion and error with a hemodialysis machine as used, e.g., in a hemodialysis clinic.

The history of hemodialysis machines extending back 30 years before *Rubalcaba* demonstrates that many thousands of patients had been treated in hundreds of clinics, and many thousands of lives had been improved and prolonged, using conventional hemodialysis equipment without "user confusion and error." Whereas needs arising specifically in hemodialysis clinics did drive the development of apparatus according to the subject claims, the "user confusion and error" addressed by Rubalcaba arises exclusively in the context of that patent, i.e., multiple separate drug-infusion modules, their coordinated operation, and potential errors from their attachment to and detachment from a stack of such modules.

Following the Examiner's contention to its logical conclusion presents a daunting question: Why did Appellants' competitors, each with a presumed knowledge of *Lichtenstein*, *Kerns*, and *Rubalcaba*, fail to develop a hemodialysis machine with a touch screen before Appellants?

For many years, hemodialysis clinics have experienced ever-increasing fiscal pressure in the face of increasing U.S. government cutbacks in reimbursement to clinics for performing hemodialysis treatments for patients with end-stage renal disease. This situation, which existed at the time of the priority date of the instant application, led to intense efforts by both Appellants and their competitors to develop (as of the priority date of the instant application) a "next generation" hemodialysis machine that addressed the clinics' concerns regarding patient safety, containment of transfection, and ease and economy of use. If the addition of a touch screen to a hemodialysis machine so as to minimize *Rubalcaba*'s "user confusion and error" was obvious, then at least one of Althin's competitors would have developed a hemodialysis machine having a touch screen before or at about the same time as Appellants did. In actual glaring fact, no competitor did so.

In view of the above, it is readily concluded that the Examiner's position regarding the posture of the subject claims relative to the cited references is hindsight reconstruction, which is an improper basis for an obviousness rejection. *In re Rouffet*, 149 F.3d at 1357-1358, 47 U.S.P.Q. 2d at 1457-1458. In examining the claims, the Examiner had the benefit of insight obtained from the extensive specification (with numerous Appendices depicting and describing the operation of the subject hemodialysis machine). The person of ordinary skill at the priority date of the instant application lacked access to such information, despite the fact that may such persons were engineers working in the hemodialysis industry. This situation begs the question: if it was so easy for the Examiner to derive the instantly claimed invention from the cited references, then why did every skilled artisan (other than Appellants) fail to make such a derivation, especially in the face of intense industry pressure to make the next generation hemodialysis machine?

Of the cited references, *Lichtenstein* arguably was confronted with the same problems as the Appellants, yet utterly failed to derive the subject claims. *Kerns* and *Rubalcaba*, on the other hand, were concerned with infusion pumps and not hemodialysis machines. Hence, *Kerns* and *Rubalcaba* were not confronted with the same problems as the Appellants and also failed to derive the subject claims. None of *Lichtenstein*, *Kerns*, and *Rubalcaba*, of course, had any knowledge of the subject claims. Similarly, none of Appellants' competitors had any knowledge of the subject claims, despite their presumed knowledge of the cited prior art. No one other than

Appellants conceived the subject claims. The Appellants could not have had hindsight since their activity in developing the subject claims was contemporaneous; rather the Appellants had remarkably clever foresight in developing the subject claims. For the Examiner, on the other hand, opportunities for hindsight were pervasive. Hence, there is no other plausible explanation besides hindsight for the Examiner being "able," today, to regard the claimed invention as obvious from the cited references, especially when no one other than Appellants had derived the subject claims at the priority date. Without hindsight, the Examiner would not have been able to select the various claimed elements from the cited prior art references for combination in the manner claimed.

Since hindsight reconstruction does not provide a proper *prima facie* case for obviousness of the subject claims, the Board is requested to reverse the Examiner and allow the claims.

B. Objective evidence of secondary considerations of nonobviousness submitted by Appellants to traverse the rejection under 35 U.S.C. § 103(a)

Appellants are submitting herewith in a document entitled "Submission of Declaration After Final" a Declaration of John Sadler, M.D. Under 37 C.F.R. § 1.132 that was of record in the parent application, U.S. Serial No. 09/067,222. (A copy of the Affidavit is attached as Exhibit A). An obviousness rejection may be overcome by presenting evidence of secondary considerations of nonobviousness. *In re Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q. 2d at 1455. Objective indicia of nonobviousness are quite relevant to a determination of obviousness or nonobviousness, *Gambro Lundia AB*, 110 F.3d at 1579, 42 U.S.P.Q. 2d at 1384, and frequently are the most probative factors weighed in determining obviousness or nonobviousness. *Pro-Mold & Tool Co. v. Great Lakes Plastics*, 75 F.3d 1568, 1573, 37 U.S.P.Q. 2d 1626, 1630 (Fed.Cir. 1996).

Secondary considerations, such as solving a long-felt need or copying by others, often are the most probative evidence of nonobviousness. *Gambro Lundia AB*, 110 F.3d at 1579, 42 U.S.P.Q. 2d at 1384 (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 U.S.P.Q. 871, 879 (Fed.Cir. 1983)); *Pro-Mold & Tool Co.*, 75 F.3d at 1573, 37 U.S.P.Q. 2d at 1630.

A hemodialysis machine is a complex life-supporting apparatus having a large number of components and subsystems requiring accurate and precise control to ensure patient safety. As previously argued during prosecution and above, innovation in the hemodialysis field is brutally driven by the demands of contemporary medical practice and by progressive cutbacks in government payment plans covering hemodialysis treatments. On and before the priority date of the instant application, these market forces caused stiff competition in the hemodialysis machine industry to develop a revolutionary hemodialysis machine (i.e., a machine representing a substantial advance over technology as represented, for example, by *Lichtenstein*). Since Appellants and their competitors all were aware of the ongoing need for improved hemodialysis equipment, a number of research and development efforts were undertaken by all entities in the market; Appellants had the foresight to conceive that, inter alia, adding a touch screen was the best development option. The subject claims represent the first conception and development of a hemodialysis machine with a touch screen, as achieved by Appellants. Sadler Declaration, ¶ 16.

The prior art is utterly silent on combining a touch screen with a hemodialysis machine, despite the fact that - as evidenced by a large body of patents and other literature concerning hemodialysis - many corporations and individuals were intensively involved, at the time of the priority date, in innovation in the hemodialysis industry. If adding a touch screen to a hemodialysis machine had been obvious at the priority date of the present application, then this intense competition should have led at least one other corporation or entity - e.g., at least one of the competitors - to develop the subject of the pending claims. However, no such simultaneous invention occurred. Instead, the claimed invention was "a truly novel and surprisingly innovative development in the market of hemodialysis machines," leading virtually every competitor in the hemodialysis industry to copy Appellants' combination of a touch screen with a hemodialysis machine, as presently claimed. Sadler Declaration, ¶ 16-17.

Appellants earned numerous design awards for the company's hemodialysis machine that embodies the subject claims: the "System 1000® Dialysis Delivery System" (termed herein the "System 1000", but at one time briefly named the "SATRN" machine). The System 1000 addressed a number of long-felt needs in the hemodialysis industry, and the most innovative feature of the System 1000 - the touch screen - was rapidly and universally copied by competitors. These secondary considerations, taken together, amply demonstrate that adding a

touch screen to a hemodialysis machine was not obvious on the priority date of the present application.

1. The numerous design awards Appellants earned for a hemodialysis machine that embodies the subject claims indicate that the subject claims are not obvious.

The System 1000 received the following major international design awards: a "Best of Category" award from the *International Design 1991 Annual Design Review*, the Industrial Design Excellence Award (IDEA) presented by the Industrial Designers Society of America; and the Design Prize of the State of Baden-Württemberg, Germany (one of only six chosen designs so honored). The touch screen is the key feature of the System 1000 (Sadler Declaration, ¶ 10) and was an important reason - if not *the* principal reason - why the System 1000 won these design awards.

For example, *International Design* magazine reported that:

> [t]he jurors [of the International Design 1991 Annual Design Review] were equally impressed with the logic and simplicity of the System 1000's interaction design. A complex series of analog knobs and dials was replaced by a touch screen loaded with self-prompting software. This feature reduced the amount of training required of dialysis personnel, reduced the margin of operator error, and allowed operators to devote more time to their patients and less to the machine.

International Design 1991 Annual Design Review, page 64. See Exhibit B. Furthermore, *International Design* stated, "The . . . System 1000 . . . [simplifies] a tremendous number of very complicated details, resulting in a clean and uncluttered solution." In view of the very large number of conventional discrete controls and displays (all of which would otherwise have to be accommodated somewhere on the front panel of a conventional hemodialysis machine, creating an inevitable impression of great complexity) that were replaced by the touch screen on the System 1000, it is inconceivable that *International Design*'s impression was not created in large part by the use of a touch screen in the System 1000 to produce the noted clean and uncluttered characteristic of the machine.

Similarly, the Design Prize of the State of Baden-Württemberg, Germany, was awarded to the System 1000 based to a large extent on the inclusion of a touch screen because "[t]he form [of the machine] is simple and clean with obvious controls and an eye-level visual display." Since the touch screen of the System 1000 provides essentially all the machine's controls, and since the touch screen is situated at the top of the machine at eye level, it is immediately apparent that the quoted comment is directed to the touch screen and not to a feature or features unrelated to the touch screen. Moreover, with respect to this award, the System 1000 was described as "[t]he pinnacle of excellence" because it not only "brought a new dimension of value" to the product, but also "improved the safety and productivity of users" of the product. The latter benefit especially is a direct benefit of the touch screen. *International Design 1991 Annual Design Review*, page 61.

These design awards are a testament to the fact that the System 1000, a direct embodiment of the subject claims in that it is the first hemodialysis machine to include a touch screen, represents a revolution in the hemodialysis industry that was developed after years of effort. Dori Jones Young, *Dialysis, Gently*, BUSINESS WEEK, page 78 (17 June 1991). In fact, Dr. John Sadler, a noted expert in the field of hemodialysis machines, considers the System 1000 "the most innovative hemodialysis machine developed in the past fifteen years and one of the most innovative pieces of medical instrumentation [he has] seen in [his] career." Sadler Declaration, ¶ 9.

If including a touch screen to a hemodialysis machine as instantly claimed had been an obvious innovation, then the development of the System 1000 machine would not have required extensive development efforts, would not have caught the attention of professional designers and business people, and would not have been cited as a basis for earning several prestigious design awards. If the subject claims were indeed obvious from the cited prior art, then such extensive and intensive research and development leading to the System 1000 would not have been necessary.

2. The claimed invention was highly successful in the marketplace.

The System 1000 was highly successful in the marketplace. For example, two months after the System 1000 was released into the marketplace, Althin could not meet customer demand. Dori Jones Young, *Dialysis, Gently,* BUSINESS WEEK, page 78 (17 June 1991), ("[Althin] began selling the machine in March and already has more orders than it can deliver."). The commercial success of the System 1000 was also discussed in *International Design*:

> The System 1000 has been highly successful. Orders are well above projection, and operators and patients alike have generated a constant stream of positive remarks and feedback. At one trade show, a dialysis technician was so excited about the new design that she literally hugged the machine.

International Design 1991 Annual Design Review, page 65.

The System 1000 has all the mechanical features of prior art hemodialysis machines: a blood pump, a heparin pump, a dialysate proportioner, pressure monitors, temperature monitors, conductivity monitors, blood line clips, an IV pole, etc. These particular features were well known in the art as of the priority date of the present application and were incorporated in many (if not all) of competing machines. The key difference between the System 1000, embodying the subject claims, and competing machines was the user interface in the System 1000 - the touch screen - as indicated by all of the evidence of record.

If the touch screen had been an obvious innovation on the priority date of the present application, then Althin would not have enjoyed the commercial success it did (before competitors began copying the touch screen), and the System 1000 certainly would not have been so warmly received at trade shows.

3. The claimed hemodialysis machines including a touch screen solved several long-felt needs in the hemodialysis industry.

Prior-art hemodialysis machines had several problems, which the claimed invention solved. For example, prior art hemodialysis machines had many buttons, switches, dials and knobs, which were prone to malfunction and required regular replacement. Sadler Declaration, ¶ 10; *Dialysis Machine Speeds Treatment and Repairs*, WALL ST. J (20 May 1991). In

hemodialysis machines according to the subject claims, at least some of these mechanical devices are replaced with a touch screen, thus eliminating troublesome sources of malfunction inherent to conventional hemodialysis machines. Sadler Declaration, ¶ 10.

Additionally, as discussed above, spaces, crevices, and hidden surfaces around and under controls and displays of prior-art hemodialysis machines readily trap germs and bodily fluids. *Dialysis Machine Speeds Treatment and Repairs*, WALL ST. J. (20 May 1001), Exhibit C; Dori Jones Young, *Dialysis, Gently*, BUSINESS WEEK, page 78 (17 June 1991). In hemodialysis machines according to the subject claims, at least some of these control mechanisms are replaced with a smooth, uniform, and crevice-free control surface for easy cleaning and minimal entrapment of germs and fluids. Dori Jones Young, *Dialysis, Gently*, BUSINESS WEEK, page 78 (17 June 1991), *see also*, Sadler Declaration, ¶ 14(b).

In addition, learning to operate prior-art hemodialysis machines required extensive training. *Dialysis Machine Speeds Treatment and Repairs*, WALL ST. J. (20 May 1991), *accord*, Sadler Declaration, ¶ 12 ("operators of other [prior art] hemodialysis machines (lacking a touch screen) generally require several hours of training, including one to three days with a training nurse on-site who instructs and helps solve problems."). In hemodialysis machines as claimed, at least some of the mechanical switches, knobs and dials found on conventional machines were replaced with a touch screen (that can also readily incorporate operator prompts and other menu-driven indicia for ease of operation and minimal error), thereby reducing operator training time. Sadler Declaration, ¶ 12; *Dialysis Machine Speeds Treatment and Repairs*, WALL ST. J. (20 May 1991), *Althin CD Medical Wins Design Award for Dialysis Machine*, NEPHROLOGY NEWS & ISSUES, page 27 (July 1991). Additionally, the touch screen of the System 1000 machine facilitated a reduction in dialysis preparation time of 35%, thus allowing more direct patient care and allowing each machine to serve more patients. *Dialysis Machine Speeds Treatment and Repairs*, WALL ST. J. (20 May 1991), Exhibit A; *International Design 1991 Annual Design Review*, page 64.

The fact that the System 1000 hemodialysis machine - embodying the touch screen according to the subject claims - so effectively solved such problems, and addressed such long-felt needs, rebuts any contention that the pending claims are obvious in view of the cited art.

4. The claimed invention was quickly copied by others.

The System 1000 machine was the first hemodialysis machine to have a touch screen. Sadler Declaration, ¶ 16. As discussed above, this innovation was cited as the basis for several major design awards conferred on the System 1000. The touch screen was also a significant factor in earning the System 1000 the rapt attention of competitors in the hemodialysis industry. Since the debut of the System 1000, competitors have developed their own respective hemodialysis machines by copying Appellants' innovation, including adding touch screens. *See*, Sadler Declaration, ¶ 17.

Furthermore, Fresenius USA, Inc. - a chief competitor of Althin - touted the advantages of a touch screen in its own promotional brochure; these advantages are identical to the advantages offered by Althin's System 1000. The Federal Circuit considers such recognition of an applicant's innovation by a competitor in the market to be relevant to a determination of nonobviousness. *Gambro Lundia AB*, 110 F.3d at 1579, 42 U.S.P.Q. 2d at 1384 (Fed.Cir. 1997).

Prior to seeing the System 1000, competitors failed to independently develop hemodialysis machines incorporating touch screen technology. Rather, competitors simply have copied the touch screen feature, as well as other features, of the System 1000 for their own respective machines. Yet, even with such copying efforts, the System 1000 is still recognized as "the state of the art in hemodialysis machines today, even though it first appeared [on the market] almost ten years ago." Sadler Declaration, ¶ 15.

C. The Claims are Separately Patentable

Claim 30 requires five features in a hemodialysis machine: (1) means for delivering extracorporeal blood to a hemodialyzer; (2) means for controlling at least one extracorporeal blood parameter; (3) a user/machine interface operably connected to the means for delivering extracorporeal blood to a hemodialyzer; (4) the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operating the hemodialyzer; and (5) the touch screen adapted to permit the user, by touching the indicium, to change the parameter. Claim 30 differs from the cited prior art (*Lichtenstein*, *Kerns*, and *Rubalcaba*) in that Claim 30 requires that the subject hemodialysis machine includes a

user/machine interface including a touch screen adapted to permit the user to change an operating parameter by touching an indicium corresponding to that parameter. The cited patents by *Kerns* and *Rubalcaba* are not directed to hemodialysis machines and provide no teaching or suggestion of how to operate hemodialysis machines. *Kerns* and *Rubalcaba* also provide no teaching or suggestion of delivering extracorporeal blood to a hemodialyzer or controlling any extracorporeal blood parameters. *Lichtenstein* discloses a hemodialysis machine including a computer, but provides no teaching or suggestion of including a user/machine interface as claimed or how to go about including such an interface with a hemodialysis machine.

Claim 31 differs from Claim 30 in two ways and has a substantially different scope than Claim 30. First, Claim 31 does not specify, in the context of a hemodialysis machine, the first three features of Claim 30. Instead, Claim 31 shares two features with Claim 30: (a) a user/machine interface comprising a touch screen; and (2) permitting the user to change an operating parameter by touching an indicium displayed on the touch screen. Second, Claim 31 requires that the subject hemodialysis machine include: (1) a dialysate-delivery system; and (2) a user-machine interface operably connected to the dialysate-delivery system. In addition, the dialysate-delivery system must include at least one unit selected from the stated group. The stated features of the dialysate-delivery system are neither taught nor suggested by either *Kerns* or *Rubalcaba*. Rather, *Kerns* and *Rubalcaba* discuss drug-infusion modules. *Lichtenstein* discloses a hemodialysis machine, but provides no teaching or suggestion of including with the hemodialysis machine a user/machine interface including a touch screen as claimed.

Claim 32 is a combination of certain elements of Claims 30 and 31 because Claim 32 includes, with the subject hemodialysis machine, an extracorporeal blood-delivery system and a dialysate-delivery system. Thus, Claim 32 has a substantially different scope than either Claim 30 or 31. Also, Claim 32 also specifies that these two systems be connectable to the hemodialyzer, with the extracorporeal blood-delivery system operating in coordination with the dialysate-delivery system. Such a combination is not taught or suggested by *Kerns* and *Rubalcaba*, either alone or in combination. Claim 32 also requires. that the subject hemodialysis machine include a user/machine interface as discussed above with respect to Claims 30 and 31. As noted above, none of *Lichtenstein*, *Kerns*, and *Rubalcaba* provides any teaching or suggestion of combining such an interface with a hemodialysis machine.

Claim 33 requires that, with respect to the subject hemodialysis machine including the claimed user/machine interface, the touch screen include features as recited in Claims 30-32. However, Claim 33 requires two additional features: (1) a first system for delivering extracorporeal blood from a source to a blood compartment of a hemodialyzer; and (2) a second system for delivering dialysate from a source to a dialysate compartment of the hemodialyzer. Claim 33 also requires that these first and second systems be connected operably to each other. Hence, the first and second systems of Claim 33 individually and collectively have different scope than corresponding systems specified in any of Claims 30-32. For example, the dialysate-delivery system of Claims 31 and 32 must include at least one unit selected from the group consisting of a dialysate preparation unit, a dialysate-circulation unit, an ultrafiltrate-removal unit, or a dialysate-monitoring unit. The second system of Claim 33 need not have any of these units. Nevertheless, for reasons discussed generally above with respect to Claims 30-32 neither of these first and second systems (or their operable connection) is taught or suggested by any combination of *Kerns* and *Rubalcaba*. Moreover, as discussed above, *Lichtenstein* provides no teaching or suggestion of combining a hemodialysis machine (including a hemodialysis machine comprising the units as claimed) with the claimed user/machine interface including a touch screen.

Claim 34 shares, with respect to the subject hemodialysis machine, the dialysate-delivery system features of Claim 31, but specifies two additional features: (1) the subject hemodialysis machine must include a user/machine interface comprising a touch screen that displays information corresponding to setting of a parameter pertinent to the operation of a hemodialysis machine; and (2) the subject hemodialysis machine must allow the user to perform one step of a procedure for changing the setting of the parameter. Thus, Claim 34 has a substantially different scope than any claim in any of the other groups. As discussed above, neither *Kerns* nor *Rubalcaba* teaches or suggests the specified dialysate-delivery system, either alone or in combination with a hemodialysis machine. Moreover, the cited prior art (either alone or in combination) does not teach or suggest operably coupling the specified user/machine interface including a touch screen to the recited dialysate-delivery system.

Claim 37 requires that the subject hemodialysis machine include the user/machine interface including a touch screen as recited in Claim 34. However, Claim 37 also requires that the subject hemodialysis machine include a means for delivering extracorporeal blood to a hemodialyzer. The extracorporeal blood delivery system must have either a blood-circulating unit, a blood-monitoring unit, or both. Also, the extracorporeal blood delivery means must be operably connected to the specified user/machine interface. Thus, Claim 37 has different scope than any of the other pending independent claims, but is distinguishable from the cited prior art for reasons as discussed above pertaining to features in common with Claim 37.

Claim 40 is essentially a combination of the user/machine interface including touch screen features of Claims 34 and 37 with the dialysate-delivery system and extracorporeal blood-delivery system of Claim 32. Thus, Claim 40 has different scope than any of the other pending independent claims, but is distinguishable from the cited prior art for reasons as discussed above pertaining to features in common with Claim 40.

Claim 41 is essentially a combination of the touch screen specified in Claim 31 with a dialysate delivery system for supplying dialysate to a hemodialyzer, similar to Claims 31, 34, and 40. However, rather than having specified units (e.g., dialysate-preparation unit, dialysate-circulation unit, etc.), the dialysate delivery system of Claim 41 must control either dialysate temperature, dialysate concentration, or both. Thus, Claim 41 has different scope than any of the other pending independent claims. Claim 41 is distinguishable from the cited prior art for reasons as discussed above pertaining to features in common with Claim 41.

D. This Board should reverse the Examiner's rejections and allow all claims as pending

The Examiner committed reversible error by maintaining his rejection under 35 U.S.C. § 103(a) without having established a *prima facie* case of obviousness. It is respectfully submitted that the Examiner erred because his rejection was based on hindsight analysis rather than a teaching or suggestion to combine the cited prior art references.

Even if a *prima facie* case of obviousness had been made (and Appellants make no such admission herein), the substantial evidence of secondary considerations proves nonobviousness of the subject claims.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

APPENDIX

30. A hemodialysis apparatus, comprising:

(a) means for delivering extracorporeal blood to a hemodialyzer and for controlling at least one extracorporeal-blood parameter selected from the group consisting of (i) blood-flow rate, (ii) arterial pressure, (iii) venous pressure, and (iv) anticoagulant delivery to the extracorporeal blood; and

(b) a user/machine interface operably connected to said means for delivering extracorporeal blood, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

31. A hemodialysis apparatus, comprising:

(a) a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and

(b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

32. A hemodialysis apparatus, comprising:

(a) a dialysate-delivery system connectable to a hemodialyzer for supplying dialysate to the hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit;

(b) an extracorporeal blood-delivery system connectable to the hemodialyzer for routing extracorporeal blood to the hemodialyzer in coordination with the dialysate-delivery system, the extracorporeal blood-delivery system comprising at least one unit selected from a group consisting of (i) a blood-circulating unit, and (ii) a blood-monitoring unit;

(c) a controller connected to and controllably operating the dialysate-delivery system and the extracorporeal blood-delivery system; and

(d) a touch screen connected to the controller, the touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis apparatus and to permit a user, by touching the indicium, to cause a change in the parameter.

33. A hemodialysis apparatus, comprising:

(a) first and second systems operably connected with each other, the first system being operable to deliver extracorporeal blood from a source to a blood compartment of a hemodialyzer, and the second system being operable to deliver dialysate from a source to a dialysate compartment of the hemodialyzer; and

(b) a touch screen connected to the first and second systems, the touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the first and second systems and to permit a user, by touching the indicium, to cause a change in the parameter.

34. A hemodialysis apparatus, comprising:

(a) a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and

(b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis machine, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter.

35. The apparatus of claim 34, wherein the parameter can have a value that changes with time.

36. The apparatus of claim 34, wherein the touch screen, responsive to an operator touching the indicium, is operable to display a numerical keypad that is touchable by the operator in performing the procedure for changing the setting of the parameter.

37. A hemodialysis apparatus, comprising:

(a) an extracorporeal-blood-delivery system for supplying extracorporeal blood to a hemodialyzer, the extracorporeal-blood-delivery system comprising at least one unit selected from the group consisting of (i) a blood-circulating unit, and (ii) a blood-monitoring unit; and

(b) a user/machine interface operably connected to the extracorporeal-blood-delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis machine, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter.

38. The apparatus of claim 37, wherein the blood-circulating unit comprises a blood pump.

39. The apparatus of claim 37, wherein the blood-monitoring unit comprises at least one of a blood-flowrate controller, a venous pressure monitor, and an arterial pressure monitor.

40. A hemodialysis apparatus, comprising:

(a) a dialysate-delivery system connectable to a hemodialyzer for supplying dialysate to the hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit;

(b) an extracorporeal-blood-delivery system connectable to the hemodialyzer for routing extracorporeal blood to the hemodialyzer in coordination with the dialysate-delivery system, the extracorporeal blood-delivery system comprising at least one unit selected from a group consisting of (i) a blood-circulating unit, and (ii) a blood-monitoring unit;

(c) a controller connected to and controllably operating the dialysate-delivery system and the extracorporeal-blood-delivery system; and

(d) a user/machine interface operably connected to the dialysate-delivery system and the extracorporeal-blood-delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to the hemodialysis machine, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter.

41. A hemodialysis machine, comprising:

(a) means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and

(b) a user/machine interface operably connected to said means for controlling the dialysate parameter, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

Exhibit A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
CONNELL ET AL.
Application No. 09/067,922 Art Unit: 1723
Filed: April 28, 1998
For: METHOD AND APPARATUS FOR KIDNEY DIALYSIS
Examiner: J. Drodge
Date: September 28, 1999

DECLARATION OF JOHN SADLER, M.D., UNDER 37 C.F.R. § 1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

I, John H. Sadler, M.D., declare as follows:

1. I have read and understand the patent application of Mark E. Connell, et al., Application No. 09/067,922, entitled METHOD AND APPARATUS FOR KIDNEY DIALYSIS.

2. A copy of my *curriculum vitae* is attached hereto as **Exhibit A.**

3. From about May, 1982, to the present, I have served on the Renal Disease & Detoxification Committee of the Association for Advancement of Medical Instrumentation (AAMI). This committee creates standards for all hemodialysis devices manufactured or distributed in the United States. I have chaired this committee since about November, 1987.

4. I have been affiliated with the Panel on Gastroenterology/Urology-Nephrology Devices of the United States Food and Drug Administration (FDA) since 1988. I chaired this panel from 1987 to 1990, and I have served as a consultant to this committee since 1990. This FDA panel reviews all medical devices used in nephrology and urology, including all hemodialysis machines.

5. From about July 1994 to the present, I have served as a co-principal investigator in the Patient Outcomes Research Team on Dialysis (CHOICE) Study conducted at Johns Hopkins University. This study, funded by the Agency for Health Care Policy and Research (AHCPR), is a continuing detailed investigation and characterization of kidney dialysis patients, including their treatments and the outcomes of such treatments. The goal of the CHOICE Study was essentially to determine the most effective way to use dialysis as a treatment for kidney disease.

6. During the time period described in paragraphs 3 through 5, I have used, examined, tested, or reviewed more than 12 different hemodialysis machines from at least seven different manufacturers, including the System 1000 Dialysis Delivery System (System 1000) manufactured by Althin Medical, Inc. (Althin).

7. I understand the System 1000 is one embodiment described in the patent application referenced in paragraph 1.

8. From about 1999 to the present, worked as a consultant for Althin. My services have included commenting on developments, offering advice on clinical practice, and attending advisory meetings. While I have received monetary compensation from Althin for these services, I receive no direct financial or other economic benefit from sales of the System 1000.

9. I believe the System 1000 is the most innovative hemodialysis machine developed in the past fifteen years and one of the most innovative pieces of medical instrumentation I have seen in my career.

10. The key feature of the System 1000 is its touch screen. The touch screen replaces a number of necessary electromechanical moving parts and control mechanisms (such as switches, buttons, and dials) of hemodialysis machines. The moving parts of control mechanisms of previous hemodialysis machines were prone to malfunction and needed regular replacement. By replacing most of the moving parts of control mechanisms with a touch screen, the System 1000 eliminated many sources of malfunction inherent in other hemodialysis machines existing at the time the System 1000 made its commercial debut.

11. Additionally, the touch screen of the System 1000 is capable of displaying more information than its contemporary competitor instruments were capable of displaying, and the information displayed on the touch screen of the System 1000 can be changed by changing screens.

12. Moreover, the touch screen of the System 1000 is surprisingly intuitive in its use. Operators of the System 1000 need very little training to be proficient in its use. For example, sixteen System 1000 hemodialysis machines for the IDF Rotunda Center associated with the University of Maryland School of Medicine were ordered in 1992. The machines were due to be delivered in August 1992 but due to shipping difficulties, did not actually arrive until September 1992. Due to these shipping problems, Althin was unable to provide a training nurse to train the Center staff. However, using only a few pages copied from the System 1000 operating manual and some assistance from telephone conversations with an Althin technician, we were able to set up all of the System 1000 machines within a few hours over a weekend and began using them on patients the following Monday (without the assistance of a training nurse). I do not believe we could have accomplished these tasks with any other hemodialysis machine available at the time since operators of other hemodialysis machines (lacking a touch screen) generally require several hours of training, including about one to three days with a training nurse on-site who instructs and helps solve problems.

13. While almost all hemodialysis machines use microprocessors, the System 1000 was the first to employ a complete computer, including a motherboard. Because of this computer, the System 1000 machine is easy to program (using the touch screen) and has proved to be surprisingly stable and reliable. Thus, the touch screen represents an important and substantial technical advancement in hemodialysis machine technology, especially when viewed in light of other hemodialysis machines available at the time the System 1000 made its debut.

14. I believe other unique and innovative features of the System 1000 include: (a) its tall and slender profile, which takes up very little floor space; (b) its smooth control surface, which prevents liquids from seeping into the machine, a common cause of malfunction in other hemodialysis machines; (c) the placement and layout of blood tubing is so obvious that instruction is not necessary—an operator can intuitively know how blood tubing should be placed simply by looking at the machine; (d) the clamp that holds the dialyzer was cleverly designed and remains better than similar clamps on other hemodialysis machines; and (e) the design allows easy maintenance and servicing.

15. While other manufacturers have tried to develop a hemodialysis machine that is simple to use, reliable, and easy to maintain, I believe the System 1000 remains the state of the art in hemodialysis machines today, even though it first appeared almost ten years ago.

16. I know of no other hemodialysis machine that was manufactured with a touch screen prior to the System 1000. While other machines used a screen to display data and error functions, such screens were much different than the touch screen of the System 1000 because they could not be used to control the machine itself.

17. At the time the System 1000 was released, it represented a truly novel and surprisingly innovative development in the market of hemodialysis machines. In this regard, I have noticed that virtually every competitor of Althin has developed, since the System 1000 made its debut, a respective hemodialysis machine that includes many of the innovations that first appeared in the System 1000.

18. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further, these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

Date: 29 Sept, 1999

John H. Sadler, M.D.

CURRICULUM VITAE

John Holland Sadler, M.D.

Associate Professor of Medicine
Division of Nephrology
Department of Medicine
University of Maryland School of Medicine
Baltimore, Maryland 21201

Mailing address:
Independent Dialysis Foundation
840 Hollins Street
Baltimore, Maryland 21201

Born: December 10, 1935
Greenville, South Carolina

Citizenship: U.S.A.

Married, 2 adult children

EDUCATION

1960	M.D., B.S. in Medicine, Duke University School of Medicine
Internship 1960-1961	Intern in Medicine Emory University School of Medicine Grady Memorial Hospital Atlanta, Georgia
Residency 1963-1964	Emory University School of Medicine V.A. Hospital Atlanta, Georgia
Fellowship 1961-1963	Fellow in Renal Disease Emory University School of Medicine Grady Memorial Hospital Atlanta, Georgia

LICENSURE Maryland, North Carolina, Georgia (inactive)

MILITARY SERVICE

1964-1966	U.S. Air Force: Chief, Internal Medicine Section U.S. Air Force Hospital Sheppard Air Force Base, Texas

FACULTY POSITIONS

1966-1967	Instructor in Medicine Emory University School of Medicine Clinical Director Atlanta Artificial Kidney Center Atlanta, Georgia
1967-1969	Assistant Professor of Medicine Emory University School of Medicine Director Atlanta Artificial Kidney Center
1969-1971	Associate Professor of Medicine Emory University School of Medicine Director Atlanta Regional Nephrology Center Grady Memorial Hospital Atlanta, Georgia
1971-1972	Associate Professor of Medicine Associate Chief Division of Renal Disease Medical College of Virginia Richmond, Virginia
1972-1992	Associate Professor of Medicine Head, Division of Nephrology University of Maryland School of Medicine Baltimore, Maryland
1992 - 1994	Associate Professor of Medicine Nephrology Division University of Maryland Baltimore, Maryland
1994 -	Clinical Associate Professor of Medicine Nephrology Division University of Maryland Baltimore, Maryland

PROFESSIONAL MEMBERSHIPS

American Federation for Clinical Research
American Society of Nephrology
International Society of Nephrology
American Society of Artificial Internal Organs
Intl. Society for Artificial Organs
American Society of Transplant Physicians
Association for Advancement of Medical Instrumentation (Chair, Renal Disease & Detoxification Committee 1987 -)
Southeastern Dialysis & Transplant Association
(President 1968)
Renal Physicians Association
(President 1973-1975, Board 1973-1981, Counselor 1981-1988)
Southeastern Organ Procurement Foundation
(President 1974-1975), Chair, Ethics Committee 1988 -1990), Chair Computer Application Committee 1976-1988)
Baltimore City Medical Society
Medical & Chirurgical Faculty of Maryland
American Medical Association
American Association for the Advancement of Science
Kidney Foundation of Maryland
(President 1978-1980)
National Kidney Foundation
Maryland High Blood Pressure Coordinating Council
(1978-1982)
American Heart Association, Council on the Kidney
Royal College of Physicians, Edinburgh, Fellow 1996.

EXTERNAL APPOINTMENTS

Maryland Commission on Kidney Disease 1981 - 1990
(Chairman 1985-1990)
Center for Devices & Radiological Health,
Food and Drug Administration
(Panel on Gastroenterology/Urology -
Nephrology Devices, Member 1986,
Chairman 1987-1990, consultant 1990-)
ESRD Network 31
(Member 1976-1988, President 1978-1980,
Medical Review Board 1981-1988)
Kidney Disease Coalition, Chair 1981-1982
(national organization to produce study,
meeting, publication on dialyzer reuse.)
United Network for Organ Sharing
Ethics Committee Member 1978 - 1992, Chair 1993-1995
Association for Advancement of Medical Instrumentation
Chair, Renal Disease & Detoxification Committee 1982 -
International Standards Organization
Renal Replacement, Detoxification & Apheresis Group
(Chairman 1982-)
Mid-Atlantic Renal Coalition (parent of ESRD Network 5)
(Board Member 1987-)
Combined Health Agencies
(Board Member 1978 - 1994,
Development Committee 1987-1988
Executive Committee 1990 -1994)
United Way of Central Maryland
(Board Member 1981-1989)
Judicial Board, University of Maryland at Baltimore
(Member 1983-1988, Chairman 1988- 1994)
Institute of Medicine, National Academy of Science,
ESRD Program Study Committee 1988-1990
Organizing Committee,
Conference on Monitoring & Managing Quality
in ESRD 1992.
Conference on Health & Functional Status
in ESRD 1994
Medical Technology & Practice Patterns Institute; Chair, Technical
Advisory Committee 1992 -

Independent Dialysis Foundation, President and CEO 1979-
Medical Education Institute: Life Options Rehabilitation
Advisory Council; Member 1993 -1998, Chair 1996-1998.
CHOICE Study, Johns Hopkins University (AHCPR funded
5 year ESRD Patient Outcome Research Team)
Co-Investigator 1994-1999.
ESRD Health Status Outcomes Group, Chair 1995-1997.

HONORS, AWARDS

1960	Borden Undergraduate Research Award Duke University
1983	SEOPF Upjohn Award
1987	AOA Medical Honor Society (Faculty)
1987	Senior Class Teaching Award
1988	Honorary Life Member, Renal Physicians Association
1991	FDA Comissioner's Award
1996	Fellow, Royal College of Physicians, Edinburgh

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